PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200400341 WO	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/DK2005/000190	International filing date *(day/month/year)* 21.03.2005	Priority date *(day/month/year)* 26.03.2004
International Patent Classification (IPC) or national classification and IPC INV. A61M5/158		
Applicant UNOMEDICAL A/S ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.07.2005	14.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Schönleben, J Telephone No. +31 70 340-2436

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2005/000190

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-17	as originally filed

Claims, Numbers

1-17	received on 21.07.2005 with letter of 18.07.2005

Drawings, Sheets

1/27-27/27	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-17
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-17
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 03/026728 A (MAERSK MEDICAL A/S; MOGENSEN, LASSE, WESSELTOFT; GOERANSSON, MAGNUS, W) 3 April 2003 (2003-04-03)
D2: FR-A-2 752 164 (VYGON) 13 February 1998 (1998-02-13)

2.1 Document D1 discloses (see page 13, line 33, to page 15, line 28, and fig. 13 to 16; the references in parentheses applying to this document) an injector device for the subcutaneous introduction of a cannula of an infusion part into the skin of a patient, said device comprising a housing (210), a back (280) and a longitudinally extending guiding means (228), a member (230) which is longitudinally slidable within the housing, an insertion needle (2129 for insertion of said cannula (226), a spring (236) located between the back (280) of the housing and the longitudinally slidable member (230), locking means (235) for maintaining the spring in a compressed state and release means (235) for disengaging the locking means and a pivoting member (219) which can be swung from a position in which the pivoting member allows insertion of the needles into a position in which it embraces the needle.

The subject-matter of claim 1 differs from this state of the art in that the pivoting member is fastened to the slidable member (instead of being fastened to the housing).

As such, the subject-matter of claim 1 is new (Article 33(2) PCT).

2.2 The technical problem to be solved by the subject-matter of claim 1 may therefore be regarded as to provide an injector device for an infusion set which device allows a safe handling.

2.3 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

With the pivoting member fastened to the slidable member, the pivotable member has

not to close an opening in the housing, through which the slidable member and its needle extend in the forward position, so that the pivotable member can be constructed as a rather short member allowing easy and therefore safe handling. However, the sliding member and pivotable member have to be constructed such that the pivoting of the pivotable member does not influence the sliding of the slidable member in its guiding means.

Document D 1 only discloses a connection of the pivoting member to the housing. Therefore,

Document D2 discloses an injector device comprising a housing, a slidable element arranged in the housing and a needle pivotally connected to the slidable element such that the needle can pivot from a protected position in the housing to an extended position and back from the extended position into the housing once the slidable element is moving to its forward or backward position, respectively. As such, there is no pivotable element embracing the needle in its extended position.

Claim 2 to 17 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII
Certain defects in the international application

The drawings do not meet the requirements of Rule 11.13(a) to (c) and (f) PCT

Re Item VIII
Certain observations on the international application

Claims 1, 4 to 7 and 9 to 14 do not meet the requirements of Article 6 PCT.

In claim 1, line 3, it is not clear that the housing comprises the back and the longitudinally extending guiding means, that the insertion needle is extending from the front part of the slidable member and that the sliding member is sliding along the longitudinally extending guiding means.

In claims 4 and 6 it appears not to be clear whether the needle is bent by the pivoting

member or the needle itself is provided at an angle to the housing.

In claim 5 it is specified that "the pivoting member *can* embrace the needle when the slidable member is in the forward position and the spring in the released state". These features in the apparatus claim relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. As such, it is not clear how the injector device has to be constructed in order to allow the pivoting member to embrace the needle only when the slidable member is in its forward position. Also the further features of claim 5 are specified in the same unclear way but these further features are specified as optional features (preferably) only so that they do not have any limiting effect (see PCT/GL/ISPE/I, Part II, chapter 5.40).

Claim 7 again relates to a method of use instead clearly defining the apparatus in terms of technical features.

Claim 9 and its dependent claims 10 to 14 define the injector device by the infusion part although the infusion part is not part of the injection device of claim 1. In claim 1 the injector device is only specified as being *suitable for* the subcutaneous introduction of the cannula of an infusion part which means that the infusion part is not part of the injector device (see PCT/GL/ISPE/I, Part II, chapter 5.37).

The embodiments described on pages 9 to 12 and shown in figures 1 to 5 do not fall within the scope of the claims. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear, Article 6 PCT.

PATENT CLAIMS: 18 July 2005

1. An injector device for the subcutaneous introduction of the cannula (5) of an infusion part (0B) into the skin of a patient said device comprising a housing (30), a back (33) and longitudinally extending guiding means (31), a member (32) which is longitudinally slidable within the housing (30), an insertion needle (35) for insertion of said cannula, a spring (34) located between the back of the housing and the longitudinally slidable member, locking means for maintaining the spring in a compressed state and release means (39) for disengaging the locking means, the device further comprises a pivoting member (36) which can be swung from a position in which the pivoting member (36) allows for insertion of the needle (35) into a position in which it embraces the needle characterized in that the pivoting member (36) is fastened to the slidable member (32).

2. An injector device according to claim 1, characterized in that the position where the pivoting member (36) allows for insertion of the needle (5) is in an angle v where $90° \leq v \leq 180°$, preferably v is approximately 90°.

3. An injector device according to claim 1, or 2, characterized in that when the pivoting member (36) is in the position where it embraces the needle, the pivoting member is placed approximately parallel to the housing.

4. An injector device according to claim 1, or 2, characterized in that when the pivoting member (36) is in the position where it embraces the needle, the pivoting member is placed in an angle w to the housing where $0° < w \leq 180°$, preferably $90° \leq w \leq 180°$.

5. An injector device according to any one of claims 1 - 4, characterized in that the pivoting member (36) can embrace the needle when the slidable member (32) is in a forward position and the spring (34) in a released state,

and preferably also the pivoting member (36) can embrace the needle when the slidable member (32) is in a retracted position and the spring (34) in a tightened state.

6. An injector device according to claims 1, characterized in that the pivoting member is swung from the position essentially orthogonal to a main axis of the application device, 180 degrees to another position embracing the needle and being secured in this position said position also being essentially orthogonal to said main axis.

7. An injector device according to any one of claims 1 to 6, characterized in that the needle is destroyed and secured in the pivoting member when the pivoting member is brought to finally embrace the insertion needle.

8. An injector device according to claim 1, characterized in that the device further comprises locking means (45) for maintaining the pivoting member in the final embracing position.

9. An injector device according to claim 1, characterized in that the infusion part (0B) is unreleasably fastened to an adhesive support (1) having an adhesive surface which adhesive surface is provided with a release liner (9).

10. An injector device according to claim 9, characterized in that the pivoting member (36) has fixing means (44) for releasably fastening a part of the adhesive support (1) to the pivoting member.

11. An injector device according to claim 9 or 10, characterized in that a projecting part of the release liner of the adhesive support (1) is fastened unreleasably to the housing (30).

12. An injector device according to claim 9, characterized in that the release liner of the adhesive support comprises at least two separate pieces (41, 42).

13. An injector device according to claim 12, characterized in that each piece of release liner has at least one projecting part.

14. An injector device according to claim 13, characterized in that the projecting part of a first piece of release liner (41) is attached to the pivoting member (36) during insertion and the projecting part of a second piece (42) of release liner is attached to the housing (30) during insertion.

15. An injector device according to claim 1, characterized in that the housing has stopping means (43), preferably a stopping tab.

16. An injector device according to claim 1, characterized in that the slidable member (32) is constructed of a lattice structure.

17. An injector device according to claim 1, characterized in that the release means (39) for disengaging the locking means comprises two positions placed on opposite sides of the housing (30).